World Journal of Gastroenterology
Editorial Board

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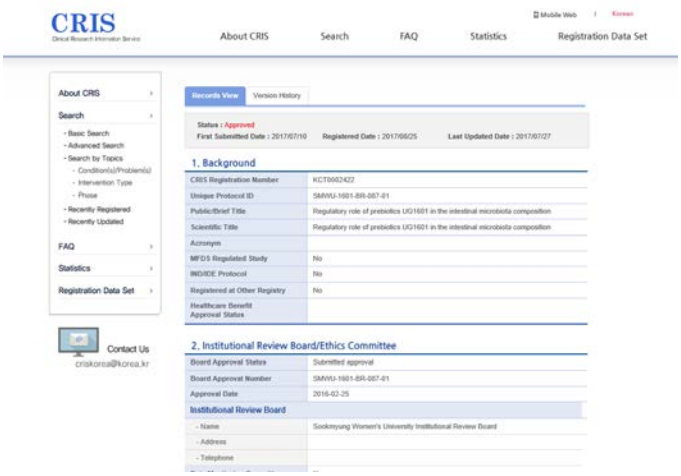
Clinical trial registration: This registration policy applies to registry trials. This study is registered with the Clinical Research Information Service (https://cris.nih.go.kr) (KCT0002422).



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Background

Scientific Title	Regulatory role of prebiotics UG1601 in the intestinal microbiota composition			
CRIS Registration No.	KCT0002422			
Healthcare Benefit Approval Status				
MFDS Regulated Study	No	Registered at Other Registry	No	-

Contact Details & Status

Contact Person for Principal Investigator / Scientific Queries	Mi-kyung Sung	Sookmyung Women's Hospital			
Study Site	Multi-center (Number of center : 2)	Name of Study Site	Sookmyung Women's Hospital,Unigen		
Overall Recruitment Status	Completed	Primary Completion Date	2016-05-21	Study Completion Date	2017-06-01
Target Sample Size	40	Date of First Enrollment	2016-03-18	Status of First Enrollment	Actual

Source of Monetary/Material Support & Sponsor Organiztion

Source of Monetary/ Material Support 1	Unigen
Sponsor Organization 1	Sookmyung Women's Hospital

Study Summary

Lay Summary	The balance between harmful bacteria and beneficial bacteria plays a key role to maintain gastrointestinal health. Therefore, development of effective material that regulates gut microbial composition is needed. The aim of this study was to assess effects of prebiotics UG1601 supplementation composing of indigestive polysaccharide compound on gut microbial composition change and endotoxemia markers in healthy human subjects.

Study Design

Study Type	Interventional Study	Study Purpose	Others	Phase	해당사항없음(Not applicable)
Intervention Model	Parallel	Blinding/ Masking	Double	Allocation	RCT
Intervention Type	Dietary Supplement	Number of Arms	2		
Intervention Description	Forty healthy subjects received either prebiotics (thirteen grams per day) or placebo for 4 weeks.				

Arm 1	Arm Label	Placebo group	Target Number of Participant	20	Arm Type	Placebo comparator
	Arm Description	Placebo group was received 13 grams of maltodextrin which was dissolved in 20ml of water for 4 weeks.				
Arm 2	Arm Label	Experimental group	Target Number of Participant	20	Arm Type	Experimental
	Arm Description	Experimental group was received 13 grams of prebiotics UG1601 which was dissolved in 20ml of water for 4 weeks.				

Subject Eligibility

Condition(s) / Problem(s)	* Diseases of the digestive system Mild-Constipation			Rare Disease	No
Gender	Both	Age	19(Year) ~ 65(Year)	Healthy Volunteers	No
Inclusion Criteria	● Healthy grown-up subjects without gastrointestinal disease ● Stool freuquency is not less than 3 times per week				
Exclusion Criteria	● Subjects who have IBD ,IBS or other gastrointestinal disease or have those medical history ● Subjects who take currently prebiotics, probiotics or synbiotics				

Outcome Measure(s)

Type of Primary Outcome	Efficacy			
Primary Outcome 1	Outcome	Relatvie abundance of butyrate-producing bacteria	Timepoint	At the basline and end of the intervention
Primary Outcome 2	Outcome	Blood endotoxemia markders (Lipopolysacchraide, CD14)	Timepoint	At the basline and end of the intervention
Secondary Outcome 1	Outcome	Fecal short chain fatty acid concentration	Timepoint	At the basline and end of the intervention

Study Results and Publication

Results	40 subjects who participated in this study and 40 subjects completed intervention study(Male: 10 persons/ Female: 30 persons). Subjects were equally divided into two groups (5 male and 15 female persons were allocated in one group). Average age of placebo and prebiotics groups were 28.40 and 24.05 respectively. There was no serious adverse effect because of perbiotics UG1601. Compliance of placebo and experimental groups were 98% and 99% respectively. Serum CD14 and LPS concentrations were significantly decreased in prebiotics group compared to placebo group. The relative abundance of Roseburia hominis, butyrate-producing bacteria, was significantly increased in prebiotics group compared to placebo group. In microbiome analysis, Firmicutes phylum and its subordinate taxonomic ranks including clostridia class, clostridiales order and Lachnospiraceae family were decreased in prebiotics responder group compared to non-responder group. There was no significant difference in fecal short chain fatty acids between placebo and prebiotics groups.
Number of publications	0

Sharing of Study Data (Deidendified Individual-Patient Data, IPD)

Sharing Statement	No